

U.S. National Phase of PCT/GB03/01123
Preliminary Amendment dated: September 16, 2004

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1(original). A seal for a valve for use in a pharmaceutical dispensing device, which seal is formed from an elastomeric composition comprising:

- (a) an isobutylene polymer or co-polymer thereof;
- (b) a cross-linking agent for the isobutylene polymer or co-polymer thereof, wherein the cross-linking agent is sulphur or a sulphur-donating compound, and wherein the cross-linking agent is free of peroxide curing agents; and

- (c) an accelerator for the cross-linking agent, wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.

2(original). A seal as claimed in claim 1, wherein the elastomeric composition comprises one or more of polyisobutylene, polybutene, butyl rubber, halogenated butyl rubber, including derivatives thereof.

3(original). A seal as claimed in claim 2, wherein the elastomeric composition comprises bromobutyl rubber and/or chlorobutyl rubber, including derivatives thereof.

4(currently amended). A seal as claimed in claim 1 ~~any one of the preceding claims~~, wherein the elastomeric composition comprises a blend of an isobutylene polymer or co-polymer thereof and a chlorine-substituted diene polymer or co-polymer thereof.

5(original). A seal for a valve for use in a pharmaceutical dispensing device, which seal is formed from an elastomeric composition comprising:

- (a) a chlorine-substituted diene polymer or co-polymer thereof;

(b) a cross-linking agent for the chlorine-substituted diene polymer or co-polymer thereof, wherein the cross-linking agent is sulphur or a sulphur-donating compound, and wherein the cross-linking agent is free of peroxide curing agents; and

(c) an accelerator for the cross-linking agent, wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.

6(original). A seal as claimed in claim 5, wherein the elastomeric composition comprises a chlorine-substituted butadiene polymer.

7(original). A seal as claimed in claim 6, wherein the elastomeric composition comprises 2-chlorobuta-1,3-diene.

8(currently amended). A seal as claimed in claim 1 ~~any one of the preceding claims~~, wherein said polysulphide compound is derived from a substituted xanthic acid or derivative thereof.

9(currently amended). A seal as claimed in claim 1 ~~any one of the preceding claims~~, wherein the substituted group in said polysulphide compound is an isopropyl group.

10(currently amended). A seal as claimed in claim 1 ~~any one of the preceding claims~~, wherein said polysulphide compound is diisopropyl xanthogen polysulphide.

11(currently amended). A seal as claimed in claim 1 ~~any one of the preceding claims~~, wherein said polysulphide compound comprises three or more bridging sulphur atoms.

12(currently amended). A seal as claimed in claim 1 ~~any one of the preceding claims~~, wherein said polysulphide compound is substantially free from nitrogen, phosphorus and metallic elements.

13(currently amended). A seal as claimed in claim 1 ~~any one of the preceding claims~~, wherein the elastomeric composition comprises up to 3 wt.% of the accelerator based on the total weight of the accelerator and polymer in the composition.

14(original). A seal as claimed in claim 13, wherein the elastomeric composition comprises up to 1.5 wt.% of the accelerator based on the total weight of the accelerator and polymer in the composition.

15(currently amended). A seal as claimed in claim 1 ~~any one of the preceding claims~~, wherein the weight ratio of the accelerator to the cross-linking agent in the elastomeric composition is in the range of from 1:1 to 3:1.

16(currently amended). A seal as claimed in claim 1 ~~any one of the preceding claims~~, wherein the seal further includes a mineral filler.

17(original). A seal as claimed in claim 16, wherein the mineral filler is selected from one or more of magnesium silicate, aluminium silicate, silica, titanium oxide, zinc oxide, calcium carbonate, magnesium oxide magnesium carbonate, magnesium aluminium silicate, aluminium hydroxide, talc, kaolin, clay and amino silane coated clay.

18(currently amended). A seal as claimed in claim 1 ~~any one of the preceding claims~~, wherein the seal further includes a process aid, preferably a low molecular weight polyethylene.

19(currently amended). A seal as claimed in claim 1 ~~any one of the preceding claims~~, further comprising one or more of a reinforcement agent, a plasticizer, a binder,

a stabilizer, a retarder, a bonding agents, an antioxidant, a lubricant, a pigment, a wax, a resin, an antiozonants, a secondary accelerator or an activator.

20(currently amended). A valve for use in a pharmaceutical dispensing device having a seal as defined in claim 1 ~~any one of claims 1 to 19~~.

21(original). A pharmaceutical dispensing device having a valve as claimed in claim 20.

22(original). A pharmaceutical dispensing device as claimed in claim 21 which is a pharmaceutical metered dose aerosol inhaler device.

23(currently amended). A dispensing apparatus for dispensing pressurised fluid comprising a valve body defining a chamber, a valve member extending movably through the chamber and through at least one annular seal co operating with the valve member and the body to regulate the discharge of fluid, wherein the or at least one of the seals is as defined in claim 1 ~~any one of claims 1 to 19~~.

24(currently amended). A dispensing apparatus which comprises a pressurised dispensing container having a valve body provided with two annular valve seals through which a valve member is axially slidable, said seals being disposed at inlet and outlet apertures of a valve chamber so that the valve functions as a metering valve, wherein at least one of the annular valve seals is as defined in claim 1 ~~any one of claims 1 to 19~~.

25(currently amended). A dispensing apparatus as claimed in claim 23 ~~or claim 24~~, comprising a pressurised dispensing container operatively connected to the valve body and containing the fluid to be dispensed and a hydrofluorocarbon propellant comprising propellant type 134a or 227.

26(currently amended). A dispensing apparatus as claimed in claim 23 ~~any one of claims 23 to 25~~, wherein the fluid to be dispensed comprises a liquid or particulate product as a solution or suspension in a carrier liquid comprising alcohol.

27(original). A dispensing apparatus as claimed in claim 26, wherein the alcohol comprises ethanol.

28(original). A seal as claimed in claim 1, which seal comprises a vulcanisate of an isobutylene polymer or co-polymer thereof, a cross-linking agent for the isobutylene polymer or co-polymer thereof, and an accelerator for the cross-linking agent, wherein the cross-linking agent is sulphur or a sulphur-donating compound and is free of peroxide curing agents, and wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.

29(original). A seal as claimed in claim 5, which seal comprises a vulcanisate of a chlorine-substituted diene polymer or co-polymer thereof, a cross-linking agent for the chlorine-substituted diene polymer or co-polymer thereof, and an accelerator for the cross-linking agent, wherein the cross-linking agent is sulphur or a sulphur-donating compound and is free of peroxide curing agents, and wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.

30(original). A process for the preparation of a seal for a valve for used in a pharmaceutical dispensing device, the process comprising:

(i) forming a composition comprising a mixture of an isobutylene polymer or co-polymer thereof, a cross-linking agent for the isobutylene polymer or co-polymer thereof, and an accelerator for the cross-linking agent, wherein the cross-linking agent is sulphur or a sulphur-donating compound and is free of peroxide curing agents, and wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof;

- (ii) initiating a cross-linking reaction in the mixture to form a cross-linked elastomeric composition; and
- (iii) either before or after (ii) forming the composition into a seal.

31(original). A process for the preparation of a seal for a valve for use in a pharmaceutical dispensing device, the process comprising:

- (i) forming a composition comprising a mixture of a chlorine-substituted diene polymer or co-polymer thereof, a cross-linking agent for the chlorine-substituted diene polymer or co-polymer thereof, and an accelerator for the cross-linking agent, wherein the cross-linking agent is sulphur or a sulphur-donating compound and is free of peroxide curing agents, and wherein the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof;
- (ii) initiating a cross-linking reaction in the mixture to form a cross-linked elastomeric composition; and
- (iii) either before or after (ii) forming the composition into a seal.

32(currently amended). A process as claimed in claim 30 ~~or claim 31~~, wherein the step of forming the composition into a seal involves one or more forming techniques selected from compression moulding, injection moulding and extrusion.

33(currently amended). A process as claimed in claim 30 ~~any one of claims 30 to 32~~, wherein the process also involves washing the seals.

34(currently amended). A process as claimed in claim 30 ~~any one of claims 30 to 33~~, wherein the seals are immersed in an aqueous chlorinated solution.

35(original). A process as claimed in claim 34, wherein the aqueous chlorinated solution comprises water and HOCl.

U.S. National Phase of PCT/GB03/01123
Preliminary Amendment dated: September 16, 2004

36(currently amended). A process as claimed in claim 30 ~~any one of claims 30 to 35~~, wherein the seals are immersed in a solution comprising water and sodium dichloroisocyanurate (NaDCC).